# BACKGROUND PAPER FOR HEARING

## CALIFORNIA STATE BOARD OF PHARMACY

### IDENTIFIED ISSUES, QUESTIONS FOR THE BOARD, AND BACKGROUND CONCERNING ISSUES

**GENERAL INFORMATION:** The California State Board of Pharmacy (Board) was created by the California Legislature in 1891. The Board is responsible for enforcing federal and state laws pertaining to the acquisition, storage, distribution and dispensing of dangerous drugs (including controlled substances) and dangerous devices. The Board has approximately 76,000 licensees in 12 license categories that include both personal and business licenses. The regulation of pharmacy through the licensing of pharmacists, pharmacies, and pharmacy technicians is the primary focus of Board activity, with consumer protection at the core of the Board's operations.

As a regulatory agency whose mandate is to protect the public, before issuing any license the Board ensures that businesses are in compliance with specific rules and regulations, and that individuals satisfy the Board's requirements for minimum competency as demonstrated through experience and/or achievement of a successful score on a licensure examination.

**PRIOR SUNSET REVIEW:** The Board was last reviewed by the Joint Legislative Sunset Review Committee (JLSRC) six years ago (1996-97). The JLSRC reviewed whether licensing and regulation of the practice of pharmacy should continue and found that there was sufficient evidence that the unregulated practice of pharmacy could cause significant public harm. The JLSRC recommended continuing the Board and directed the Board to implement a number of recommendations and changes. Some of these recommendations included: (1) the addition of one public member to the composition of the Board; (2) the Governor should attempt to assure that all professional members of the Board are representative of all aspects of the pharmacy profession; (3) the requirement that all inspectors for the Board be licensed pharmacists should be eliminated; (4) regulatory authority of other state agencies over certain licensing classifications should be consolidated under the Board as well as any overlapping of duplicative licensure requirements for any of the Board's licensing classifications; (5) an electronic monitoring system should be implemented to obtain timely, accurate, and complete data for preventing drug diversion of controlled substances; (6) the Board should be allowed to conduct fingerprint checks for criminal histories of applicants; and (7) a public awareness campaign should be funded and implemented.

In September 2002, the Board submitted its required sunset report to the JLSRC. In this report, information of which is provided in Members' binders, the Board described actions it has taken since the Board's prior review. The Board addressed several issues presented during its last review. Over the course of the last six years, the Board has, among other things:

- Sponsored legislation to require all pharmacies to develop a Quality Assurance Program to help prevent prescription errors.

- Expanded its authority to issue a citation and fine for any violation of pharmacy law.
- Implemented a number of Internet-based services for the public and licensees.
- Convened the Pharmacy Manpower Task Force to identify possible solutions to the shortage of pharmacists in California.
- Sponsored and funded an electronic monitoring system for the dispensing of Schedule II controlled substances (CURES) to identify diversion.
- Received two awards for its public education and consumer outreach program.

The following are unresolved issues pertaining to this Board, or areas of concern for the JLSRC, along with background information concerning the particular issue. There are also questions that staff has asked concerning the particular issue. The Board was provided with these issues and questions and is prepared to address each one if necessary.

# CURRENT SUNSET REVIEW ISSUES

## ***BOARD COMPOSITION ISSUES***

**ISSUE #1: The Board currently consists of 11 members: seven professional members and four public members. This composition provides for a super majority of professional members.**

**Question #1 for the Board:** *Should the ratio of licensee to public member be changed to increase the number of public members? Does the Board view greater public representation as beneficial to itself and to the consumer? Would the Board support legislative efforts to increase public membership?*

**Background:** The Board indicates in its sunset report that it believes the current size and composition of the Board allows all members an opportunity to participate in committee and Board activities and discussions.

Over the past eight years, requiring closer parity between public and professional members is consistent with JLSRC and Department of Consumer Affairs (DCA) recommendations for other boards that have undergone sunset review. Generally, a public member majority for occupational regulatory boards, or greater representation of the public where current board membership is heavily weighted in favor of the profession, is preferred for consumer protection. Since any regulatory program's primary purpose is to protect the public, increasing the public's representation on this Board assures the public that the profession's interests do not outweigh what is in the best interest of the public.

At the time of its last review, the Board was comprised of seven professional members and three public members. Pursuant to the recommendations of the Joint Committee, one public member was added to the composition of the Board.

**ISSUE #2: Current law requires five of the seven pharmacist members of the Board to be pharmacists who are actively engaged in the practice of pharmacy. It seems that the current makeup of the Board may not meet this requirement.**

**Question #2 for the Board:** *How many pharmacists are currently serving on the Board? Of those members, how many are actively engaged in the practice of pharmacy? What is the Board's interpretation of "actively engaged in the practice of pharmacy?"*

**Background:** Business and Professions Code Section 4001 specifies the composition of the Board: seven pharmacists and four public members. Of the seven pharmacists members, five must be active practitioners. It appears that there may be only two Board members that could be considered as actively engaged in the practice of pharmacy.

## *BOARD COMMITTEE ISSUES*

**ISSUE #3: The Board has five standing committees each of which develops policy in its respective area and makes recommendations to the full Board. It is unclear which committee meetings are open to the public and which are not.**

**Question #3 for the Board:** *How many members make up each committee? Who determines which members are on which committees? Does every committee have at least one public member? If not, why not? Is every committee meeting held in a public forum? What determines which committee meetings are public? Does the Board believe that the public should be able to provide input at all committee meetings?*

**Background:** The Board has the following standing committees: Communication and Public Education Committee; Licensing Committee; Legislation and Regulation Committee; Enforcement Committee; and Organizational Development Committee.

There does not seem to be any consistency in what committees are held in a public forum or the membership of the committees.

**ISSUE #4: For many years prior to 2002, the Board maintained a "Southern Compliance Committee" (SCC) and a "Northern Compliance Committee" (NCC).**

**Question #4 for the Board:** *What did these committees do? Were the members of these committees Board members or non-Board members? What statute authorized these committees to exist? Do these committees still exist? If not, who/what committees are doing the work that used to be done by the NCC/SCC?*

**Background:** The Compliance Committees operated for more than 25 years to meet with licensees who had been subjects of Board inspections or investigations for violations of law that were not serious enough to be referred to the Attorney General's (AG) Office for formal discipline. Nevertheless, these were violations of law identified by Board inspectors. As such, two or three Board members would convene these meetings to publicly discuss the violations with the pharmacist, pharmacist-in-charge and management. The Board states that the goal was compliance and correction through a "peer review" process with Board members.

The Compliance Committees were disbanded in early 2002 with the formation of the Citation and Fine Committee. According to the Board, the new committee structure was needed because legal counsel had advised the Board that the Compliance Committees might run afoul of provisions in the Government Code and be inconsistent with provisions in the citation and fine regulation.

## *LICENSURE ISSUES*

### ISSUE #5: The Board is pursuing a change in statute that allows the pharmacist-in-charge and the pharmacist on duty to determine the number and combination of ancillary personnel that he or she may supervise.

**Question #5 for the Board:** *What is the current ratio? What is the proposed change in ratio? Please expand on and provide justification for the Board's proposed legislative changes to the pharmacist to staff ratio. What type of discretion would the pharmacist have in determining these ratios? Would this modification in ratio benefit the consumer as well as the profession?*

**Background:** Currently, a community pharmacist can supervise one pharmacy technician, one intern, one technician trainee, and one clerk-typist. This is a one to four ratio. A second pharmacist in a community pharmacy is allowed to supervise two technicians. In a hospital inpatient pharmacy and in a pharmacy that services long-term care facilities or home health patients, the ratio is one pharmacist to two pharmacy technicians, for a total of one to five.

The Board's proposed legislative change would allow a pharmacist to supervise four ancillary personnel and it defines ancillary personnel as a pharmacist intern, pharmacy technician, and pharmacy technician trainee. According to the Board, the proposed changes in ratios come from recommendations of the Pharmacy Manpower Task Force Report.

### ISSUE #6: The vast majority of denied applications for licensure are pharmacy and pharmacy technician applicants.

**Question #6 for the Board:** *What criteria does the Board use to deny applications? Why have so many pharmacy applicants been denied in the past year? Historically, why do pharmacy technician applications have a higher rate of denial than other applications?*

**Background:** Since 1998/99, nearly 55% of the applications denied by the Board were from pharmacy technician applicants. However, in 2001/02, 60% of the applicants denied were from pharmacy applicants.

**ISSUE #7: The Board voted at its October meeting to move forward on revising registration and program requirements for pharmacy technicians. Proposed statutory and regulatory changes would include, among other things, certification by the Pharmacy Technician Certification Board (PTCB) as a qualifying method to becoming a pharmacy technician.**

**Question #7 for the Board:** *Please discuss the proposed revisions to the pharmacy technician registration and program requirements and why the Board believes such changes are necessary. At this time, how does becoming certified by the PTCB benefit a pharmacy technician? Is the Board considering having PTCB certification as the sole qualifying method, thereby limiting the avenues by which one could qualify to become a pharmacy technician? If so, would the Board have any type of testing, in addition to the PTCB, to take into account California law?*

**Background:** The original technician registration and program requirements have been in place for over 10 years. Although there have been some program modifications such as technician trainees, a ratio increase for the second pharmacist in the community setting, and mandatory registration of all pharmacy technicians, there has not been a major review or update of the program.

Based on the recommendations of the Pharmacy Manpower Task Force and others, the Board is proposing the following revisions to the pharmacy technician registration and program requirements: 1) accept PTCB certification; 2) accept the associate degree in pharmacy technology and eliminate the other associate degrees; 3) revise the specificity of the theoretical and practical requirements of the training curriculum; 4) accept graduation from a school of pharmacy; and 5) eliminate the "equivalent experience" provision for the clerk-typist and hospital pharmacy technician.

**ISSUE #8: In the past few years, there has been a rise in the applications for licensure. Specifically, in the last four years, there has been over 100% increase in applications in five licensing categories.**

**Question #8 for the Board:** *To what does the Board attribute this steady growth in applications? Describe what effects this increase has had on the licensing program.*

**Background:** Since 1998/99, the Board has received increasing numbers of applications from: pharmacy technicians (up 156%); pharmacies (up 146%); pharmacy interns (up 142%); foreign graduates (up 123%); and pharmacists (up 108%).

**ISSUE #9: In 1998, the Board granted a waiver to Cedars-Sinai Medical Center and Long Beach Memorial Medical Center to allow technicians to check other technicians as a study with UCSF, School of Pharmacy. Subsequently, the Board issued an extension of the waiver until December 2002. At its last meeting, the Board granted an additional year extension to these entities.**

**Question #9 for the Board:** *Why is the waiver continually extended? What are the results of the study to date? Is there a need for the issue to be explored further? Does the Board intend on pursuing or supporting legislation to allow technicians to check technicians?*

**Background:** In May 1998, the Board granted a waiver pursuant to Board regulations to the University of California School of Pharmacy in conjunction with Long Beach Memorial Medical Center (LBMC) and Cedars-Sinai Medical Center (CSMC) to permit a study of technicians to check technicians for unit-dose medication cassette distribution system in the inpatient setting. The waiver was initially granted until November 1, 2000, was extended until December 2002, and was recently extended by another year.

At the Board's January 2001 meeting, LBMC and CSMS reported that technicians functioning in the study have consistently met or exceeded the minimum target rate of 99.8% accuracy. The Board voted at that time to proceed with legislation or a regulation change to allow technicians to check technicians in inpatient settings if there is a quality assurance program in place, certification, audit review, and ongoing checking.

## ISSUE #10: What are the educational requirements to apply for a pharmacist license? Are the requirements changing in the near future?

**Question #10 for the Board:** *Does the Board or the pharmacy schools anticipate any new changes to the educational requirements to become a pharmacist, i.e., requiring a PharmD degree? If so, please describe the process (i.e., legislative and/or regulatory) that will take place or has taken place to increase the educational requirements. Will there be/was there public input to the process? What additional requirements must be met to obtain a PharmD Degree? Why and on what basis were these deemed necessary?*

**Background:** The current educational requirement to apply for a pharmacist license is a degree from a college of pharmacy or department of a university with 150 or more semester units of study and at least a Bachelor of Science degree in pharmacy.

# *BUDGETARY ISSUES*

## ISSUE #11: The Board projects a deficit situation in the coming fiscal year as a result of a loan made to the General Fund.

**Question #11 for the Board:** *What efforts did the Board undertake to forewarn what an enormous impact the transfer/loan would have on the Board's budget? Is the Board planning on setting forth regulations to increase fees? If the loan is promptly repaid, will the Board still pursue an increase in fees? Has a repayment schedule been requested by the Board? If so, what is it?*

**Background:** This year $6 million was transferred in the form of a loan from the Board's fund to the General Fund. Consequently, the Board projects a deficit situation in the coming fiscal year. The

Board has indicated that unless the money is repaid early in FY 2003/04, then it will be forced to reduce expenditures substantially or increase fees to the statutory maximum.

The Board has indicated that it will work in conjunction with the DCA Budget Office and the Department of Finance to closely monitor its fund condition.

## ISSUE #12: The Board consistently exceeds its AG budget.

**Question #12 for the Board:** *Please explain why the Board continues to overspend its AG budget? Has the Board sought a deficiency request to augment its spending authority? Has the Board had to suspend actions on disciplinary cases pending at the AG's Office? If so, to what extent has this occurred?*

**Background:** Lack of AG funding has been a growing problem over the years, and the Board has made repeated and only partially successful attempts to obtain budget change proposal augmentation for the AG budget.

The Board's AG budget for 2002/03 is $777,475, which includes an adjustment of $80,576 for increased Attorney General rates and $6,670 for the new sterile compounding licensure program. Removing this adjustment leaves an AG budget of $690,229.

Actual AG expenditures over the prior years have been: $642,178 in 1998/99; $832,708 in 1999/00; $860,036 in 2000/01; and $963,651 in 2001/02.

During the first two months of FY 2002/03, the Board spent $153,000 on AG services. Should the Board continue to spend at this average level, it will overspend its AG budget by $140,000. The Board believes it will need to submit a deficiency request in late winter 2002 to enable it to continue its needed level of AG services.

## ISSUE #13: The Board has projected that expenditures will continue to surpass revenue in the future.

**Question #13 for the Board:** *Please provide an analysis of the Board's fund condition for FY 98/99 and 99/00. Have the expenditures been exceeding revenue for more than two years? Why has there been such a huge jump in expenditures from FY 00/01 to 01/02? Why is the Board's revenue projected to remain relatively constant over the next four years even though the licensee population has been increasing? Does the Board believe that the licensee population is going to level off? What steps has the Board taken to address its perceived budget problems?*

**Background:** Over the last two fiscal years, the Board's expenditures consistently have surpassed revenue. The Board has projected this trend to continue into the next four fiscal years. From FY 2000/01 to FY 2001/02, there is a jump in expenditures of $900,0000 and expenditures are forecasted to keep increasing while income remains constant.

**ISSUE #14: According to the Board, staff resources "are not sufficient to provide consumer protection at desired levels." The Board further indicates in its sunset report that specialized programs used to target pharmacies suspected of illicit activities are not optimally operating due to limited staff resources.**

**Question #14 for the Board:** *What does the Board consider "desired levels" of consumer protection? Is the public at risk because of insufficient staff resources? Are other programs being affected by staff vacancies due to the hiring freeze? Has the Board sought hiring freeze exemptions for the positions that are vacant? If so, what is the status of that (those) request(s)? Is the Board in danger of losing additional "vacant" positions as a result of the recently revised 6-month abolishment provision in the Government Code? If so, what effect will such losses have and what does the Board plan to do about it? How many vacant staff positions did the Board lose as a result of the latest budget bill? If any, what classifications were they?*

**Background:** All of the Board's operations are being affected by staff vacancies and the hiring freeze. The Board has only 50 plus staff, and is viewed as its own hiring authority. As such, it can only fill positions with existing Board staff unless a freeze exemption has been obtained. This creates a hardship when any position is vacant because every position is vitally needed and existing staff must absorb the workload or work must be reprioritized to assure the most essential duties are performed.

Since October 2001, the Board has been unable to fill six of seven positions. As a result, a number of Board services have been cut or eliminated. Further, the Board lost four vacant positions due to budget language that eliminated vacant positions.

## *EXAMINATION ISSUE*

**ISSUE #15: There has been controversy surrounding the Board's proposal to seek approval for use of the North American Pharmacist Licensure Exam (NAPLEX) instead of the current state examination.**

**Question #15 for the Board:** *Please expand on the examination options that the Board has been exploring. What was the outcome of the NAPLEX assessment? What is the Board's position on the use of the NAPLEX? Has the Competency Committee recommended the use of the NAPLEX? Does being the only state not to use the national exam affect California in any way?*

**Background:** The Board commissioned a group of experts to conduct an independent audit of the NAPLEX. The audit results revealed that the NAPLEX is a suitable test of competency for entry to practice pharmacy in California, and its development and administration conformed with the specified requirements in state law relating to professional licensing examinations.

According to the National Association of Boards of Pharmacy, all other 49 states, as well as United States territories of Guam and Puerto Rico, use the NAPLEX. To ensure knowledge of state specific pharmacy laws, states typically require applicants, in addition to the NAPLEX, to take a state specific jurisprudence exam related to the specific profession.

# ***PHARMACIST SHORTAGE ISSUES***

## **ISSUE #16: California is experiencing a pharmacist shortage and projections for the future indicate that the population will continue to increase at a higher rate than the pharmacist population thereby exacerbating the problem.**

**Question #16 for the Board:** *What specific efforts is the Board making to deal with this crisis and what recommendations does the Board have to resolve the current, and prevent the future shortages of pharmacists in the state? Is addressing the pharmacists shortage part of the Board's strategic plan? Would the use of the NAPLEX examination ameliorate the pharmacist shortage in California, by enabling licensed and qualified pharmacists from other states to become licensed more easily (without examination) in California?*

**Background:** According to a study published in December, 2000, by the United States Department of Health and Human Services, "The Pharmacist Workforce: A Study of the Supply and Demand for Pharmacists," the evidence clearly indicates the emergence over the past few years of a shortage of pharmacists. The study found that there has been an unprecedented demand for pharmacists and for pharmaceutical care services, and the factors causing the current shortage are of a nature not likely to abate in the near future without fundamental changes in pharmacy practice and education. Factors causing the shortage include a 44% increase in the number of retail prescriptions dispensed per year in the United States between 1992 and 1999, and a 32% increase in the number of prescriptions filled per pharmacist during the same time period. According to this study, the pharmacist supply in California was at 54 pharmacists per 100,000 population, well below the nationwide average of 68 per 100,000.

The ability to obtain a license in a different state by health care professionals who are licensed in another state is often referred to as licensing reciprocity. Reciprocity laws vary from profession to profession and from state to state and hinge largely on whether or not the state's licensing board utilizes a national exam, versus a state-specific exam. Licensing reciprocity between states is easier when the states use the same national exam. Currently, California has a state-specific pharmacy exam, which makes licensing reciprocity more difficult. Use of this exam may stimulate reciprocity licensure of out-of-state pharmacists and may help alleviate the pharmacist shortage in the State.

## **ISSUE #17: It is unclear which recommendations resulting from the Pharmacy Manpower Task Force (Task Force) were considered or are going to be considered by the Board.**

**Question #17 for the Board:** *Please describe the results of Task Force. How many issues did the Task Force concentrate on? Of the issues that the Task Force focused on, how many did they take a position on? What recommendations from the Task Force has the Board acted upon, or intends to act upon? Did the Task Force take a position on the use of NAPLEX?*

**Background:** The Board conducted a series of five Task Force meetings throughout the State during 2001. The purpose of the Task Force was to address the pharmacist shortage in California and generate

a set of proposed solutions to be submitted to the Board for review and action. All Task Force meetings were open to the public. The Task Force issued its final report in November 2001 and the Board considered the recommendations at its January 2002 meeting.

The Task Force was comprised of 15 members that included two Board members who were also members of the Licensing Committee. The 15-member Task Force included representatives from the four California schools of pharmacy, the California Pharmacists Association, the California Society of Health-System Pharmacists, three pharmacist labor organizations (the Guild for Professional Pharmacists, the California Employee Pharmacists Associations, and the United Food and Commercial Workers, Local 324), the California Retailers Association, the California Association of Health Plans, and a consumer member.

The Task Force considered 27 proposals but only made recommendations on 16 of the proposed solutions.

## ***ENFORCEMENT ISSUES***

### ISSUE #18: The Board does not have a Chief of Enforcement nor does the position exist.

**Question #18 for the Board:** *How is the enforcement program managed without a Chief? Does the Board view a Chief of Enforcement as a vital component of the enforcement program? What steps has the Board taken to create such a position and hire someone to fill it?*

**Background:** Currently, the management of the Board's enforcement program is shared by the executive officer, the assistant executive officer, two supervising inspectors and one staff services manager. It is unclear if this is the most efficient and/or effective way of managing the Board's enforcement program and if an enforcement chief would provide a better system.

### ISSUE #19: The Board's citation and fine authority was recently expanded to include any violation of pharmacy law. Now, a Cite and Fine Committee made up of two Board members assesses the fines instead of the executive officer.

**Question #19 for the Board:** *Please explain why the Board made these modifications to the program. Can an inspector issue a citation and/or fine to a pharmacist or pharmacy? If not, why not? Why did the Board begin using Board members to issue cites and fines as opposed to the executive officer? What is the current composition of the Cite and Fine Committee? Who appoints the members of the Cite and Fine Committee? Does the Cite and Fine Committee always include at least one public member? Is an individual who is being cited provided an opportunity to attend and/or address the Cite and Fine Committee? After obtaining the expanded authority, did the Board go back and issue citations prior to when they had the authority to do so? How long does it take the Cite and Fine Committee to issue a citation/fine? How much does this process cost? Wouldn't it cost much less if inspectors and the executive officer were empowered to issue all citations and fines without Board member participation (as happens at most other DCA boards)? What happens if a cited/fined licensee requests a hearing before an ALJ, and the ALJ's proposed decision subsequently comes before the Board? If not, why not? Does the Cite and Fine Committee always hold public meetings? What, if any, modifications is the Board planning on making to the cite and fine process in the future?*

**Background:** In 2001, the Board amended its citation and fine authority to allow for citations of any violation of pharmacy law. Previously, the Board's authority was limited to violations of patient consultation, continuing education, or unlicensed activity.

Presently, the Citation and Fine Committee reviews investigation reports prepared by Board inspectors, and where warranted, issues citations and fines.

Executive officers of other DCA agencies are routinely permitted to issue citations and fines, however the Board's executive officer does not have the authority to issue citations and fines to a pharmacist or a pharmacy. The executive officer does have the authority to issue citation and fines for continuing education violations, unlicensed activity, failure for a pharmacy to designate a pharmacist-in-charge or file a discontinuance of business, and for violations committed by non-pharmacy licensees.

## ISSUE #20: In April 2001, the Bureau of State Audits (BSA) reported that the Board was not doing its job to investigate complaints, had excessively lengthy complaint resolution timeframes, and its system of prioritizing complaints was deficient.

**Question #20 for the Board:** *What actions has the Board taken to respond to the State Auditor's report? What is the current status regarding resolving the issues raised in the audit? Are there remaining items that still need to be addressed? What are the current complaint resolution timeframes? How does the Board prioritize complaints? Has the prioritization process changed since the BSA report was published? Have routine inspections that were suspended while investigators were used to resolve complaints resumed? Are there any backlogs in the handling of complaints, investigations, or prosecution of cases?*

**Background:** In March 2000, the BSA initiated an investigation of the Board under the provisions of the California Whistleblower Protection Act after receiving an allegation that the Board had a backlog of consumer complaints and was not doing its job to investigate incoming complaints. The BSA investigated and substantiated the allegation.

Specifically, the BSA found that the Board's established timeframes to resolve complaints – up to 290 days for complex complaints and 140 days for all others – were excessive when compared to the timeframes mandated by law or regulation for other consumer protection agencies. Second, the BSA found that the Board failed to meet its own excessive timeframes. Between January 1, 1994 and March 6, 2000, it took the Board an average of 441 days to close 5,265 complaints. Although the Board's goal was to complete the investigation phase of its enforcement process within five months, the BSA found that Board staff took on average nine months to complete investigations after the complaint is assigned to an inspector. Third, the BSA examined the Board's system for prioritizing complaints. Based on the subject matter of complaints, the Board categorized its high-risk complaints as Priority 1 (urgent-immediate), Priority 2 (rapid), Priority 3 (active investigation), or Priority 4 (standard, consistent turnaround). The BSA found that this system "does not ensure that complaints involving potential injury are investigated within the maximum allowed time of five months." The BSA found that, regardless of risk, the Board took longer than five months to complete about 60% of its investigations. Fourth, BSA found that the Board has not maintained adequate staff to ensure timely complaint resolution. The Board was authorized to hire only 19 inspectors and two supervising inspectors (all of whom are pharmacists) to cover the entire state of California. In FY 1999-2000, there

was a 35.7% vacancy rate for inspector and supervising inspector positions at the Board; 7.5 of the Board's 21 inspector positions were vacant. Had those positions been filled, the BSA projected that each inspector would have been able to resolve an additional 51 complaints per year and a backlog would not exist. The BSA noted that the Board believes that difference in salary paid to public sector pharmacists compared with the private sector hinders its ability to attract qualified applicants for its inspector positions.

The BSA concluded that "these concerns reflect gross inefficiency on the part of the Board. Delays in resolving complaints increase the risk that those violating pharmacy laws will continue to make mistakes that affect the public health, safety, or welfare of California consumers."

## ISSUE #21: Despite the last sunset review recommendation that the requirement that all Board investigators be licensed pharmacists be eliminated, the requirement still exists.

**Question #21 for the Board:** *What action did the Board take on the prior sunset review recommendation? Why? Why do all of the Board's investigators have to be pharmacists? Given the fact that these positions are hard to fill and the salary problems state the Board has matching private sector compensation, why is this still a requirement? Instead of being mandatory, why is it not an option that investigators be licensed pharmacists? How often does the Board use sworn peace officers from DCA's Division of Investigation?*

**Background:** During the last review of the Board, the Legislative Analyst's Office had recommended the elimination of the statutory requirement that its inspectors be licensed pharmacists, and instead allow the use of industry experts (pharmacist consultants) if the need arises for technical expertise. The recommendation was due in part to the Board's difficulty in recruiting inspectors who are licensed pharmacists because of the low salary schedules for this classification at the state level.

The Legislative Analyst's Office stated and the JLSRC agreed that the Board should have the option to hire licensed pharmacist inspectors or other state investigators. Mandating that all inspectors be licensed pharmacists is unique to this Board. Other boards do not require that only licensed professionals perform investigation or inspection of suspected violations of their respective licensing acts. Most will use expert professional witnesses as needed.

## ISSUE #22: It is unclear what reporting requirements the Board has.

**Question #22 for the Board:** *Does the Board have any reporting requirements? If not, why not?*

**Background:** Many other DCA agencies have statutory reporting requirements that provide the agency with information about post-licensure misconduct by licensees. For example, court clerks are required to report criminal convictions and civil judgments and settlements in cases concerning professional negligence or misconduct; insurance companies are required to report malpractice payouts on licensees; and licensees are required to self-report certain events.

**ISSUE #23: The Board recently created a new mediation unit within its enforcement program.**

**Question #23 for the Board:** *What kinds of complaints are being mediated? Why does it take the Board over one year to mediate 52% of the complaints referred for mediation?*

**Background:** In 2000, a specialized mediation team of non-inspector analysts was established to focus on the resolution of consumer complaints. The Complaint Mediation Team was developed and staffed by complaint analysts who mediate consumer complaints (prescription errors), research criminal convictions, and perform in-house investigations of technical violations of pharmacy law – work that does not require the knowledge of a pharmacist, such as unlicensed activity of pharmacy technicians.

## *DISCLOSURE POLICY ISSUE*

**ISSUE #24: At its October 2002 meeting, the Board voted to expand its consumer complaint disclosure policy. However, the information provided by the Board may vary depending on the method of inquiry.**

**Question #24 for the Board:** *Is the Board's revised policy consistent with the "Recommended Minimum Standards for Consumer Complaint Disclosure" issued by DCA? Does it deviate from the DCA's recommended standards? If so, how? Is the requesting party furnished with the same information regardless of the means used to make the request, i.e., telephone request, written request, or use of the Board's web page? If not, why not?*

**Background:** On July 16, 2002, the DCA distributed its "Recommended Minimum Standards for Consumer Complaint Disclosure." Other boards have begun reviewing their current disclosure policies in light of this document and suggested standards to be followed.

The Board only provides basic enforcement and licensing information over the telephone. For more complex and copies of documents, the Board requires a written request.

## *BOARD, CONSUMER AND LICENSEE USE OF THE INTERNET ISSUE*

**ISSUE #25: The Board has improved its website in many areas but it could/should be enhanced further.**

**Question #25 for the Board:** *What is the Board doing to effectively utilize internet capabilities to improve services and provide better information to consumers and licensees? Does the Board plan to implement online complaint filing? When did the Board eliminate the "Contact Us" feature from its website? What other improvements does the Board expect to make? Does the Board envision being able to implement new systems any time in the near future?*

**Background:** The Board has a website from which it conducts business with the public and licensees. For consumers and the public generally, the Board has a diversity of information including an online complaint form and information on how to file a complaint; consumer tips/patient information; submitting comments, complaints or suggestions about the Board or the DCA; and information about patient consultation and a patient's bill of rights. All Board public education brochures are available online.

The website provides license records and permits license verification, posts Board minutes, agendas, actions of the Board from the last meeting, board committee activities, and the strategic plan and quarterly program updates. The website also contains all regulations pending and recently enacted. All Board newsletters and *Health Notes* are also available from the Board's website, as are Board legislative analyses on pending legislation.

For licensees and applicants, the Board has its application forms and instructions online and background information about each licensing program, in addition to the items listed above. The Board also includes the prices of the 50 top Medi-Cal drugs, so pharmacies can obtain this information readily. Board newsletters that contain important information about pharmacy law and interpretations of Board law, and pharmacy law itself are available via the website.

However, consumers are unable to file complaints online or contact the Board via e-mail from its website and licensees are unable to obtain real-time application status information and renew a license online.

## *CONSUMER AND LICENSEE OUTREACH ISSUES*

### ISSUE #26: It is unclear when The Script was last issued.

**Question #26 for the Board:** *What is the last date The Script was published? When does the Board anticipate that The Script will next be issued? Does the Board intend to keep The Script a quarterly publication?*

**Background:** The Script is a quarterly newsletter put out by the Board; however, the newsletter has not been published in some time.

### ISSUE #27: The Board's updated Consumer Alert poster was to include an 800 number. However, it does not.

**Question #27 for the Board:** *Why does the poster not include an 800 number? Does an 800 number exist? Was the 800 number one of the planned remedies to address deficiencies outlined in the BSA audit?*

**Background:** The Board's updated Consumer Alert poster was recently approved by the Board. It is to be posted in every pharmacy to increase consumer awareness. Originally, the poster was to have an 800 number listed, but the final version does not include such a number.

## ISSUE #28: Consumer satisfaction survey shows room for improvement.

**Question #28 for the Board:** *What steps has the Board taken to address the main reasons for dissatisfaction expressed by consumers? Is a complaint satisfaction survey mailed with every complaint closure letter?*

**Background:** Currently, 65% of those filing complaints with the Board and responding to the Board's survey cards were satisfied with the Board's handling of the complaint, and 72% were satisfied with the Board's assistance to them.

Of the consumers who were not satisfied, most are unhappy with the time taken to complete the investigation, the information provided regarding the complaint's status or status of the investigation is not sufficient, or believe that the disciplinary sanctions imposed by the Board should be higher.

## ISSUE #29: According to a study conducted by the Board, only 25% of people have heard of the Board of Pharmacy and are unclear of its role.

**Question #29 for the Board:** *What has the Board done to educate the public of its existence and role?*

**Background:** In 2000, the Board conducted a survey that found that over 75% of the people surveyed had never heard of the Board of Pharmacy. Of the people who had heard of the Board, most thought the Board represents the pharmacist profession and not consumers.

# *PHARMACIST PRACTICE ISSUES*

## ISSUE #30: The Board needs to focus on a growing number of complex and far-reaching issues which are facing the State as well as the nation in the practice of pharmacy.

**Question #30 for the Board:** *Please comment on each of the following issues, specifically, whether the Board has each issue included in its strategic plan, what the timeframe is for addressing the issue, and any update or developments in the following areas of concern*:

- Prescription errors
- Prescription label accuracy
- Compounding
- Patient privacy
- Internet prescribing
- Veterinary drug regulation

## **ISSUE #31: There is evidence that patients are being charged for oral consultations on new prescriptions.**

**Question #31 for the Board:** *How does the Board ensure that pharmacists are providing oral consultations? Is the Board aware of circumstances when patients are charged for such consultations? If so, what action has the Board taken on this issue? Are such charges permissible under current law? If so, should the law prohibit such charges?*

**Background:** Pharmacists are required to offer oral consultations on all new prescriptions. There is evidence that patients are being charged for these consultations. Draft text approved by the Board's Public Education and Communications Committee for the revised Consumer Alert poster originally included language referring to no-charge consultations but that statement was not included in the final version of the poster.